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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,745	01/22/2002	Brendan M. Donohoe	057	3564

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EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,745

Applicant(s)

DONOHUE ET AL.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 2,7 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-12,16,17,20-22,25-35,37,42 and 52-61 is/are rejected.
- 7) ☒ Claim(s) 13-15, 19, 23, 24, 36, 38-41, 43-51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4,5.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

There are three patentably distinct features claimed:

1. A tool with a beveled cutter beveled inwardly or outwardly.
2. A tool wherein the piercing member allows rotation relative to the cutter, or a tool wherein the piercing member does not allow rotation relative to the piercing member.
3. A tool wherein the actuator is a flexible shaft or a coil spring.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Brian Schar on March 12, 2004 a provisional election was made without traverse to prosecute the invention of a inwardly beveled cutting member, with a fixed piercing member, a coil spring actuator, claims 1, 3-6, 8-17, 19-61. Affirmation of this election must be made by applicant in replying to this Office action. Claim 2, 7, and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. A faxed copy of the election was received and placed in the file.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

1. The information disclosure statement filed 5/8/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

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As discussed in the letter faxed to the examiner 3/10/04, the IDS and references were not available to the examiner. The examiner has searched all the US patents and publications. The foreign references and PCT documents will be considered when the references are received by the examiner. Also of note, the copy of the IDS received by the examiner is missing page 3.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "coil spring" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 42 recites the limitation "first driveshaft" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3-5, 8-12, 17, 19, 20, 22, 25, 26, 27, 30-35, 37, 42, 54, 57, 58, 60, and 61, are

rejected under 35 U.S.C. 102(b) as being anticipated by Dekel 5,591,187. Note the rejections

will flip the names of the cutting elements, as the different claim limitations require

reinterpretation of the reference. Dekel discloses, “A tool for making an incision in and

removing tissue from a vessel wall (the whole device), comprising: a cutter (13); and a piercing

member (20) positioned within said cutter, wherein said piercing member and said cutter are

configured to translate together to penetrate the wall of the vessel (the cutting members are

structured to allow the tool to move as one unit).”

5. Regarding claim 3, the piercing member is element 13 and the cutter is element 34. Note,

the piercing member and cutter are now fixed rotationally.

6. Regarding claim 4, wherein said cutter (34) is a curved blade having a substantially

circular distal end.

7. Regarding claim 5, wherein said cutter is a curved blade having an open perimeter (there

opening along the perimeter of the cutter) at its distal end and along the length of the whole

cutter.

8. Regarding claim 8, wherein the distal tip of said piercing member (13) extends further in

the distal direction than the distal end of said cutter.

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9. Regarding claim 9, wherein said piercing member (20) holds the tissue removed from the wall of the vessel (cutter is 13).
10. Regarding claim 10, wherein said cutter (13) is substantially hemostatic.
11. Regarding claim 11, wherein said piercing member is an auger.
12. Regarding claim 12, wherein said auger and said cutter are substantially coaxial.
13. Regarding claim 17, Dekel discloses "A surgical tool for removing tissue from the wall of a vessel to create an opening, comprising: a rotatable cutter (13); an auger assembly (20) fixed (fixed as in attached. To be clear, element 13 is considered to be fixed to element 20, via the rod extending from element 13) to and substantially coaxial with said cutter, said auger assembly comprising an auger (20) at its distal end; an actuator (22) connected to at least one of said auger assembly and said cutter.
14. Regarding claim 19, the actuator (21) of Dekel is attached to auger (20) via the rod (22).
15. Regarding claim 20, wherein said actuator is retractable (Dekel discloses the tool can be disassembled.)
16. Regarding claim 22, wherein said cutter is vented. Vented can be exposed to air. Such as John vented his shorts out the window. Since element 13 is movable outside the casing 18, it is considered to be vented.
17. Regarding claim 25, further comprising a casing, said casing comprising a contact structure (8) at its distal end, wherein said auger and said cutter translate relative to said contact structure.
18. Regarding claim 26, wherein said contact structure has an open perimeter.

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19. Regarding claim 27, wherein said auger and said cutter translate distally a selected amount relative to said contact structure.

20. Regarding claim 30, further comprising a seal housing (32), and an introducer tip (8) connected to said seal housing, wherein said auger (20) and said cutter (13) are configured to slide through said introducer tip.

21. Regarding claim 31, wherein said auger and said cutter are configured for withdrawal into said seal housing.

22. Regarding claim 32, wherein said introducer tip is expandable. The introducer can be inherently expanded by heating for example.

23. Regarding claim 33, wherein said seal housing comprises at least one guide (D3).

24. Regarding claim 34, further comprising a bushing (see attached sheet D1) connected to said actuator, said bushing comprising at least one guide follower (D2) configured to engage said guide.

25. Regarding claim 35, wherein said introducer defines a first axis, and wherein said guide extends away from said first axis.

26. Regarding claim 37, wherein the distal end of said auger extends distally beyond the distal end of said cutter.

27. Regarding claim 42, as best understood wherein said at least one rib (each coil in the 32 is a rib) extends substantially axially along said first driveshaft (18).

28. Regarding claim 54, Dekel discloses, "A method for creating an opening in a vessel wall within a patient, comprising: advancing a piercing member and a cutter through the vessel wall, said cutter axially fixed to and positioned at least partially around said piercing member, wherein

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said advancing cuts tissue from the vessel wall; and retracting said piercing member and said cutter, whereby the cut tissue is removed from the vessel wall to form an opening therein.”

29. Regarding claim 57, further comprising providing hemostasis at the opening. This will be done automatically by the body through the natural healing process.

30. Regarding claim 58, further comprising rotating said auger and said cutter.

31. Regarding claim 60, wherein said auger pulls the vessel wall proximally while said cutter advances distally.

32. Regarding claim 61, wherein said auger holds the tissue plug intramurally.

33. Claim 17 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Donohoe.

The cutter is element 28. The auger is 26. The two cutting elements are attached together or fixed together. However, they are not rotatably locked. The actuator is element 30.

34. Regarding claim 21, wherein said actuator extends away from the axis of said cutter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel '187 in view of Mueller 2001/0001124. Dekel discloses a sharp cutting element but does not go into detail about which direction to make the bevel to give the cutter a sharp edge. Mueller discloses a circular tissue-puncturing tool. Mueller teaches the cutting edge may be beveled inwardly or

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outwardly. At the time of the invention it would have been obvious to one having ordinary skill in the art to make the bevel of the Dekel tool beveled inwardly as taught by Mueller, because an inward bevel enables the edge to pierce the tissue.

36. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel 5,591,187. The Dekel device discloses the device of claim 17 and a handle. Dekel doesn't disclose a knob (18) operatively connected to said actuator. A knob is not disclosed. Knobs perform the same function as the handle of Dekel, allowing the actuator to be rotated. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute a knob for handle since knob would perform equally well as the handle in Dekel device.

37. Regarding claim 29, wherein said knob is rotatable through two or more positions (position A is shown in figure 1, a 90° will place the knob in position B), and wherein actuation of said auger (16) and said cutter (13) is controlled by rotation of said knob.

38. Claims 16, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel '187 in view of Donohoe et al. 2002/0082626. Regarding claim 53, the Dekel device contains an auger but does not contain a flute on the auger. The auger on the Donhoe et al. device comprises a flute. The auger of Donohoe functions to remove and hold the tissue in same manner as the Dekel device. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the Donohoe et al auger for the Dekel device since the Donohoe device is an alternate analogous structure and is capable of removing and holding a piece of tissue.

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39. Regarding claim 53, the combined Dekel has an auger of the same structure as the applicant's. Thus the auger of Dekel would inherently have the capability to pull the tissue proximally faster than said cutter advances.

40. Claims 55-56 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel 5591187 in view of Gannoe et al. 6,488,693. The Dekel device is manually operated. Dekel does suggest that this tool can be operated via a hydraulic mechanism. He also discloses that spring could apply an impulsive force in the reverse direction. The advancement of the auger isn't automated by Dekel though. Gannoe et al. discloses using a spring mechanism to advance the cutting member. This mechanism automates the manual process disclosed by Dekel. At the time of the invention it would have been obvious to one having ordinary skill in the art to automate the forward force of the Dekel device by implementing the spring mechanism of Gannoe et al., since it has been that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art.

Allowable Subject Matter

Claim 13-15, 23-24, 36, 38, 39, 40, 41, 43, 44, 45-51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 13-15, Dekel does not disclose an auger that comprises: a spike (the tip of the auger is the spike); a shaft (20) connected to and extending distally from said spike, said

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shaft fixed to said cutter. There are insufficient structural elements in Dekel to anticipate all the limitations of this claim.

Regarding claims 23 and 24, the Dekel device doesn't contain a flange that centers the auger.

Regarding claim 36, 38, 39, 40, 41, 43, 44, 45-51, the axis of the introducer and the actuator are on the same axis.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5423796 A	Trocar with electrical tissue penetration indicator
US 5423846 A	Dottering auger catheter system
US 5591187 A	Laparoscopic tissue retrieval device and method
US 6080173 A	Tissue punching instrument
US 6190392 B1	Method and apparatus for ultrasonic removal of bone cement material
US 6488693 B2	Vascular incisor and method
US 6673088 B1	Tissue punch
US 6685630 B2	Optical trocar
US 6689147 B1	Anastomosis punch device and method

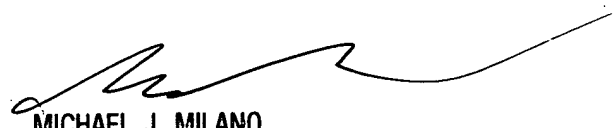
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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03/16/04



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